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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,249	09/28/2004	Shunichi Kuroda	12480-000067/US	4499
30593 7590 03/23/2007 HARNES, DICKEY & PIERCE, P.L.C. P.O. BOX 8910 RESTON, VA 20195			EXAMINER GUDIBANDE, SATYANARAYAN R	
			ART UNIT 1654	PAPER NUMBER
			MAIL DATE 03/23/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>APPLICATION NO./ CONTROL NO.</b> 10509249	<b>FILING DATE</b> 9/28/04	<b>FIRST NAMED INVENTOR / PATENT IN REEXAMINATION</b> Kuroda, Shunichi	<b>ATTORNEY DOCKET NO.</b> 12480-000067/US
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**EXAMINER**

Satyanarayana Gudibande

**ART UNIT****PAPER**

1654

20070315

DATE MAILED:

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**Commissioner for Patents**


The reply filed on 2/8/07 is not fully responsive to the prior Office Action because of the following omission(s) or matter(s): Applicants were required to elect a single disclosed species of particle forming protein (with a SEQ ID NO., representing the protein and elect a single species of a 'encapsulating substance' as the nature of the 'substance' is unknown. Applicants argue that the election restriction is improper stating that "[T]he Applicants further note that with respect to nucleotide sequences, MPEP § 803.04, although recognizing that nucleotide sequences are usually deemed to constitute independent and distinct inventions within the meaning of 35 U.S.C. § 121, provides that: to further aid the biotechnology industry in protecting its intellectual property without creating an undue burden on the Office, the Commissioner has decided *sua sponte* to partially waive the requirements of 37 CFR § 1.141 et seq. and permit a reasonable number of such nucleotide sequences to be claimed in a single application. It has been determined that normally ten sequences constitute a reasonable number for examination purposes. Accordingly, in most cases, up to ten independent and distinct nucleotide sequences will be examined in a single application without restriction. In addition to the specifically selected sequences, those sequences which are patentably indistinct from the selected sequences will also be examined. Furthermore, nucleotide sequences encoding the same protein are not considered to be independent and distinct inventions and will continue to be examined together". Applicants are hereby advised that the 37 CFR 1.141 applies to only nucleotide sequences and does not apply to proteins, peptide and amino acid sequences. It should also be noted due the presence of redundancy in genetic code more than one DNA (nucleotide) sequence codes for one peptide or protein sequence. The different peptide and protein sequences are quite distinct from each other. Also, the election of species under Markush practice works according to the MPEP 803.02 as follows: "As an example, in the case of an application with a Markush-type claim drawn to the compound X-R, wherein R is a radical selected from the group consisting of A, B, C, D, and E, the examiner may require a provisional election of a single species, XA, XB, XC, XD, or XE. The Markush-type claim would then be examined fully with respect to the elected species and any species considered to be clearly unpatentable over the elected species. If on examination the elected species is found to be anticipated or rendered obvious by prior art, the Markush-type claim and claims to the

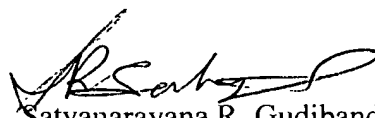
electd species shall be rejected, and claims to the nonelected species would be held withdrawn from further consideration. A second action on the rejected claims can be made final unless the examiner introduces a new ground of rejection that is neither necessitated by applicant's amendment of the claims nor based on information submitted in an information disclosure statement filed during the period set forth in 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p). See MPEP § 706.07(a). On the other hand, should **\*\*>**the examiner determine that< the elected species >is allowable<, the **\*>**examination< of the Markush-type claim will be extended. If prior art is then found that anticipates or renders obvious the Markush-type claim with respect to a *nonelected species*, the Markush-type claim shall be rejected and claims to the nonelected species held withdrawn from further consideration. The prior art search, however, will not be extended unnecessarily to cover all nonelected species. Should applicant, in response to this rejection of the Markush-type claim, overcome the rejection, as by amending the Markush-type claim to exclude the species anticipated or rendered obvious by the prior art, the amended Markush-type claim will be reexamined". With respect generic claims MPEP 818.02 states "Where only generic claims are first presented and prosecuted in an application in which no election of a single invention has been made, and applicant later presents species claims to more than one >patentably distinct< species of the invention, **\*\*>**the examiner may require applicant to elect< a single species. The practice of requiring election of species in cases with only generic claims of the unduly extensive and burdensome search". Furthermore, the restriction stated, "Applicant is advised that the reply to this requirement to be complete and must include (i) an election of species or invention to be examined even though the requirement be traversed (37 CFR 1.143). Applicant's lack of election as required resulted in an incomplete response. The 'particle forming protein' and the 'encapsulated substance' encompass numerous species of proteins and substances whose characteristics are unknown. Applicants are required to elect single species for 'particle forming protein' and the 'encapsulated substance'. See 37 CFR 1.111. Since the above-mentioned reply appears to be *bona fide*, applicant is given **ONE (1) MONTH or THIRTY (30) DAYS** from the mailing date of this notice, whichever is longer, within which to supply the omission or correction in order to avoid abandonment. **EXTENSIONS OF THIS TIME PERIOD MAY BE GRANTED UNDER 37 CFR 1.136(a).**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Satyanarayana R. Gudibande whose telephone number is 571-272-8146. The examiner can normally be reached on M-F 8-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
ANISH GUPTA  
PRIMARY EXAMINER

  
Satyanarayana R. Gudibande, Ph.D.  
Art Unit 1654